

SUMMARY OF SIGNIFICANT DIFFERENCES BETWEEN THE CURRENT AND PROPOSED 10 CFR PART 26 RULES

Significant Changes in Applicability of the Rule

- Clarify that the rule applies to new reactors constructed and licensed under 10 CFR Part 52. (§26.3)
- Continue to apply the rule to all personnel with unescorted access to the protected area of a nuclear power plant, consistent with the NRC's denial of a 10 CFR 26.6 exemption request by the International Brotherhood of Electrical Workers (IBEW) Local 1245. (§26.25)
- Prohibit the granting of temporary unescorted access to the protected areas in almost all circumstances. (§26.53)
- Clarify that there are no distinctions in the FFD requirements between licensee and contractor/vendor (C/V) personnel who are subject to the FFD requirements. (§26.3)
- Provide that persons who are covered by a program regulated by another Federal or State agency that meets the performance objectives of 10 CFR Part 26 need not be subject to duplicate testing and training requirements by a licensee's FFD program. (§26.25)

Significant Changes To Enhance Consistency With HHS and DOT Guidelines and Programs

- C Add requirements for validity tests on urine specimens to determine if a specimen has been adulterated, diluted, or substituted. At the request of stakeholders, the rule would permit licensee testing facilities to perform validity screening tests using non-instrumented testing devices, as proposed by HHS on April 13, 2004 (69 FR 19672), but not yet incorporated into final HHS guidelines.
- C Add requirements for the use of oral fluids (i.e., saliva) as acceptable specimens for initial alcohol tests.

Significant Changes To Enhance the Effectiveness and Efficiency of FFD Programs

- C Substantially reorganize the rule to eliminate redundancies, group related requirements together, and present requirements in the order in which they would apply to licensee FFD processes.

Subpart B —Program Elements

- S** Emphasize the Commission's intent that the performance objective of FFD programs is to provide "high" rather than "reasonable" assurance that persons subject to Part 26 are trustworthy and reliable as demonstrated by the avoidance of substance abuse and the adverse behaviors that may accompany it. (§26.23)

- S** Revise the FFD training requirements to require all individuals subject to the rule to receive the same FFD training, including training on behavioral observation, and complete training prior to assignment to duties within the scope of Part 26; add a requirement for a comprehensive examination; allow the use of alternative training media; and allow individuals who pass a comprehensive “challenge” examination to be exempted from annual refresher training. The rule would permit licensees and other entities to accept passing a “challenge” examination that was administered by another Part 26 program to satisfy the annual refresher training requirement. (§26.29)
- S** Revise drug and alcohol testing program requirements:
 - C Allow properly monitored supervisors, co-workers, or relatives of the individual being tested to collect specimens (except for directly observed collections), but continue to restrict them from performing assessment or evaluation procedures. (§26.31(b)(1))
 - C Clarify the situations—“pre-access,” “for cause,” “post-event,” “return-to-duty,” “follow-up,” and “random”—in which testing would be required. (§26.31(c))
 - C Add requirements to include urine specimen validity testing. (§§26.131, 26.137, 26.161, and 26.167)
 - C Add a requirement that assays used for testing for drugs in addition to those specified in this part, or testing at more stringent cutoff levels than those specified in this part, would be evaluated and certified by an independent forensic toxicologist. (§26.31(d))
 - C Add a requirement that cutoff levels would be applied equally to all individuals subject to testing. (§26.31(d))
 - C Lower the blood alcohol concentration (BAC) at which a confirmatory test is required from 0.04 percent to 0.02 percent. (§26.31(d))
 - C Eliminate blood testing for alcohol. (§26.31(d))
- S** Clarify that behavioral observation would be a required element of FFD programs. (§26.33)
- S** Clarify and strengthen the due process rights of individuals undergoing a review for FFD violations. (§§26.37 and 26.39)

Subpart C—Granting and Maintaining Authorization

- S** Allow licensees to rely on other licensees’ and other entities’ Part 26 programs to meet requirements for granting and maintaining authorization. (§26.53)
- S** Clarify the time period during which an individual may be away from a Part 26 program and maintain authorization. (§26.53(b))

- S** Reduce from 5 to 3 years the period of time to be addressed by the suitable inquiry for initial applicants who do not report any potentially disqualifying FFD information on the self-disclosure. (§26.55)
- S** Increase the thoroughness of the suitable inquiry. (§26.55)
- S** Define the steps that licensees would take in granting initial authorization, authorization updates, and authorization reinstatements. The rule would relate requirements to factors such as whether the individual has held authorization before, the time elapsed since the applicant last held authorization, and whether the individual's last period of authorization was terminated favorably. (§§26.55, 26.57, 26.59)
- S** Specify the questions and define the time period that would be addressed in the self-disclosure. (§26.61)
- S** Permit licensees to rely on suitable inquiry information gathered by previous licensees and other entities who would be subject to the rule. (§26.63)
- S** Reduce the period from 60 to 30 days in which a pre-access drug test would be performed prior to assignment to activities. (§26.65(b))
- S** Clarify and strengthen requirements for re-authorizing an individual who has had a confirmed positive drug or alcohol test result and whose authorization has been terminated unfavorably. (§26.69)

Subpart D—Management Actions and Sanctions

- S** Make the minimum sanctions for violations of the FFD policy more stringent. (§26.75)
 - C** Require permanent denial of authorization for refusing to be tested or attempting to subvert the testing process. (§26.75(b))
 - C** Add a 5-year denial of authorization for resignation to avoid removal for an FFD violation. (§26.75(d))
 - C** Require unfavorable termination of authorization for 14 days for a first confirmed positive drug or alcohol test result. (§26.75(e))
 - C** Increase the authorization denial period for a second confirmed positive drug or alcohol test result from 3 to 5 years. (§26.75(e))
 - C** Add permanent denial of authorization for additional FFD violations following any previous denial for 5 years. (§26.75(g))
- S** Clarify the requirements with regard to individuals who may be impaired. (§26.77)

Subpart E—Collecting Specimens for Testing

- S** Reorganize, clarify, and specify in more detail the requirements that are currently in Appendix A. These changes would make drug and alcohol collection practices more consistent with those of other Federal agencies and would increase consistency among Part 26 FFD programs. Increased consistency would allow Part 26 programs to accept and rely on other Part 26 FFD programs for suitable inquiries, determinations of fitness, authorization decisions, and results of drug and alcohol tests. (Subpart E)
- S** Permit the use of either breath or oral fluids (i.e., saliva) for initial alcohol tests. The rule would allow only breath specimens to be used for confirmatory alcohol testing and eliminate the donor's discretion to use blood as specimen for alcohol testing. (§26.83(a))
- S** Clarify requirements for actions to be taken if an individual does not appear for testing. (§26.89)
- S** Establish requirements regarding the alcohol screening devices (ASDs) that may be used, clarify requirements for evidential breath testing (EBT) devices, and permit use of the same EBT for initial and confirmatory alcohol testing. (§26.91)
- S** Reduce the number of breath specimens required for alcohol testing from two each for initial and confirmatory testing to one each for the initial and confirmatory testing (consistent with DOT procedures for workplace alcohol testing). (§26.95)
- S** Eliminate the requirement to list medications prior to specimen collection (in compliance with the privacy requirements of the Americans with Disabilities Act). (§26.89)
- S** Consistent with DOT procedures, add detailed procedures for conducting initial and confirmatory breath alcohol tests with EBTs, and for conducting initial tests for alcohol with ASDs. (§§ 26.93, 26.95, 26.97, 26.99 and 26.101)
- S** Reduce from 0.04 percent to 0.02 percent the BAC at which a confirmatory alcohol test would be required (§26.99) and provide cutoff levels for confirmed positive alcohol test results that take into account the length of time the donor had been in a work status. (§26.103)
- S** Clarify requirements for urine specimen collection procedures and make the procedures more consistent with those of other Federal programs. (§26.105)
- S** Require donors to provide a "predetermined quantity" of at least 30 mL of urine (decreased from 60 mL in current rule) and eliminate requirements to combine successive specimens from a donor to obtain a specimen of sufficient size. (§26.109)
- S** Clarify requirements for assessing specimen validity at the collection site. (§26.111)
- S** Specify grounds to conduct a directly observed collection. (§26.115)

- S** Combine in one section requirements for safeguarding specimens and preparing them for transfer to the licensee testing facility or an HHS-certified laboratory for testing. (§26.117)
- S** Establish a process for determining whether there is a medical reason that a donor is unable to provide a urine specimen of at least 30 mL. (§25.119)

Subpart F—Licensee Testing Facilities and Subpart G—HHS-Certified Laboratories

- S** Clarify and combine requirements applicable to licensee drug testing facilities in Subpart F and combine requirements applicable to HHS-certified laboratories in Subpart G. Many requirements in Subpart F parallel requirements in Subpart G. For increased clarity, stakeholders requested that requirements for each type of laboratory be presented separately and that any requirements that apply to both types of laboratories be presented in both subparts.

Licensee Testing Facilities

- C Add cutoff levels for initial validity tests of urine specimens at licensee testing facilities and require tests for creatinine, pH, and one or more oxidizing adulterants. The rule would not allow licensees and other entities to establish more stringent cutoff levels for validity testing, and would also specify the criteria for determining that a specimen must be forwarded to an HHS-certified laboratory for further testing. (§26.131)
- C Replace and amend cutoff levels for initial tests for drugs and drug metabolites to be consistent with HHS cutoff levels. (Decrease the cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL. Increase the cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL.) (§26.133)
- C Eliminate the requirement that licensees must inform the Commission and receive written approval from the Commission before specifying more stringent cutoff levels for drugs and drug metabolites and add a requirement for more stringent cutoff levels to be evaluated and approved by an independent forensic toxicologist. (§26.133)
- C Clarify requirements concerning donor requests to test the specimen in Bottle B of a split sample. (§26.135)

HHS-Certified Laboratories

- C Add cutoff levels for validity testing at HHS-certified laboratories to be consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. (§26.161)
- C Replace and amend cutoff levels for initial tests for drugs and drug metabolites to be consistent with HHS cutoff levels. (Decrease the cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL. Increase the cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL.) (§26.163)

Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness

- S** Clarify and expand the requirements relating to qualifications, relationships, and responsibilities of the Medical Review Officer (MRO).
 - C Add a requirement that the MRO pass a certification examination within 2 years of rule implementation. (§26.183)
 - C Add specific prohibitions concerning conflicts of interest. (§26.183)
 - C Specify MRO programmatic responsibilities. (§26.183)
- S** Establish the requirements and responsibilities of the MRO Staff.
 - C Add a requirement for the MRO to be directly responsible for the activities of individuals who perform MRO staff duties. (§26.183)
 - C Add a requirement that MRO staff duties must be independent from any other activity or interest of the licensee or other entity. (§26.183)
 - C Prohibit the MRO from delegating his or her responsibilities for directing MRO staff activities to any individual or entity other than another MRO. (§26.183)
 - C Specify the job duties that MRO staff may and may not perform. (§26.183)
- S** Clarify and expand MRO responsibilities for verifying an FFD violation.
 - C Make the MRO responsible for assisting the licensee or other entity in determining whether the donor has attempted to subvert the testing process. (§26.185)
 - C Provide detailed guidance on circumstances in which the MRO may verify a non-negative test result as an FFD policy violation without prior discussion with the donor. (§26.185)
 - C Clarify MRO responsibilities when the HHS-certified laboratory reports that a specimen is invalid. (§26.185)
 - C Specify actions the MRO may take if he or she has reason to believe that the donor may have diluted a specimen in a subversion attempt, including confirmatory testing of the specimen at the assay's lowest level of detection for any drugs or drug metabolites. (§26.185)
 - C Add requirements for the MRO to determine whether a donor has provided an acceptable medical explanation for a specimen that the HHS-certified laboratory reported as adulterated or substituted. (§26.185)
 - C Incorporate HHS recommendations on verifying a positive drug test for opiates. (§26.185)

- C Incorporate Federal policy prohibiting acceptance of an assertion of consumption of a hemp food product or coca leaf tea as a legitimate medical explanation for a prohibited substance or metabolite in a specimen. (§26.185)
- C Provide detailed requirements for evaluation of whether return-to-duty drug test results indicate subsequent drug use. (§26.185)
- S** Add a new position, substance abuse expert (SAE), to the minimum requirements for FFD programs and specify the qualifications and responsibilities of the SAE. (§26.187)
 - C Specify the role of the SAE in making determinations of fitness and the return-to-duty process, including the initial evaluation, referrals for education and/or treatment, the followup evaluation, continuing treatment recommendations, and the followup testing plan. The rule would specify the role of the SAE in determinations of fitness based on the types of professional qualifications possessed by the SAE. (§26.189)

Subpart I—Managing Fatigue

- S** Establish program requirements for fatigue management at nuclear power plants.
 - C Codify a process for workers to self-declare that they are not fit for duty because of fatigue. (§26.197)
 - C Require training for workers and supervisors on symptoms of and contributors to fatigue and on fatigue countermeasures. (§26.197)
 - C Require licensees to include fatigue management information in the annual FFD program performance report that would be required under §26.217, including the number of waivers of the individual limits and break requirements that were granted, the collective work hours of any job duty group that exceeded the group average limit in any averaging period, and certain details of fatigue assessments conducted. (§26.197)
- S** Establish work hour controls for certain job functions at nuclear power plants, performed by operations, maintenance, health physics, chemistry, security and some fire brigade personnel.
 - C Establish individual work hour limits of no more than 16 hours in a 24 hour period, 26 hours in a 48 hour period, and 72 hours in a week, excluding shift turnovers. (§26.199)
 - C Establish individual break requirements of at least 10 hours between shifts, a 24-hour break in any 7 days, and a 48-hour break in any 2 weeks, with some exceptions for outages. (§26.199)
 - C Allow licensees to waive the individual work hour limits and break requirements only if necessary to mitigate or prevent a condition adverse to safety or to maintain the security of the facility and if a fatigue assessment is performed for the worker with satisfactory results. (§26.199)

- C Would not permit licensees to waive the individual work hour limits and break requirements for individuals who self-declare they are unfit due to fatigue; if a fatigue assessment performed for those individuals determined they were fit, the individuals would only be permitted to perform non-risk significant activities under the waiver. (§26.199)
- C Establish a group average limit of 48 hours/week over a 13-week calculation period. (§26.199)
 - S** The first 8 weeks of a plant outage would be exempted from the limit for non-security personnel and would be increased to 60 hours/week for security personnel. (§26.199)
 - S** Security personnel would be allowed a 60 hour/week limit during the first 8 weeks of any planned security system outages. (§26.199)
 - S** Security personnel would not be subject to any group average limit during the first 8 weeks of an unplanned security system outage or increased threat condition. (§26.199)
 - S** Successive plant outages separated by 2 weeks or less would be considered as a single plant outage for purposes of the 8-week exemption. (§26.199)
- C Allow the average work hours of any job duty group to exceed the 48 hour/week limit in one averaging period if either:
 - NRC approval is obtained, or
 - The circumstances could not be reasonably controlled, the group average does not exceed 54 hours/week, and the additional hours are worked only to address the circumstances the licensee could not have reasonably controlled. The group average would not be allowed to exceed the 48-hour/week limit in any two consecutive averaging periods without NRC approval. (§26.199)
- C Waive the individual and group limits during a declared emergency. (§26.199)
- C Waive the individual and group limits for security personnel if the NRC notifies licensees in writing that the limits are waived in order to assure the common defense and security. (§26.199)
- C Require licensees to review individual and group hours worked, including reviews for any individuals granted more than one waiver, individuals assessed for fatigue, individuals with average work hours over 54 hours/week when subject to a 48 hour/week group average, and individuals with over 66 hours/week when subject to a 60 hour/week group average limit. The rule would require licensees to record, trend, and correct, under the corrective action program, problems found with fatigue management. (§26.199)

- Require face-to-face fatigue assessments for specific post-event, for-cause, self-declaration and follow-up conditions. (§26.201)

Subpart J—Recordkeeping and Reporting Requirements

- S** Reorganize and present together recording and recordkeeping requirements that are currently in separate sections of the rule.
 - C Require submission of program performance data to the NRC every 12 months rather than every 6 months, as in the current rule. (§26.217)
 - C Require C/Vs with approved drug and alcohol testing programs to submit program performance data to the NRC. (§26.217)

Subpart K—Inspections, Violations, and Penalties

- S** Reorganize and present together the current requirements. (§§26.221, 26.223)